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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,596	03/06/2007	Larry Lapanashvili	088790-000400US	6960
20350 7590 04/14/2010 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER DIETRICH, JOSEPH M	
			ART UNIT 3762	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,596	Applicant(s) LAPANASHVILI, LARRY	
	Examiner Joseph M. Dietrich	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-103 is/are pending in the application.
- 4a) Of the above claim(s) 83-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/6/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 53 – 82) in the reply filed on January 6, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 53 – 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. **Claim 53** recites the limitation "the time interval" in line 3. There is insufficient antecedent basis for this limitation in the claim. Furthermore, the claim recites "a processor for deriving from the time interval between said periodically recurring signal peaks a time delay." However, it is unclear whether the processor or another apparatus determines the time interval.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board

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of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **claim 57** recites the broad recitation from 50 to 250 Hz, and the claim also recites 100 to 200 Hz and 150 Hz which is the narrower statement of the range/limitation. Similarly, **claim 58** recites the broad recitation from 20 to 80 Hz, and the claim also recites 30 to 50 Hz and 40 Hz.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 53 – 58, 60 – 75, 81 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krikorian (USPN 4,541,417) in view of Karasev et al. (USPN 5,257,623).

Regarding **claim 53**, Krikorian discloses a sensor for detecting recurring R-R peaks of an electrocardiogram (e.g. 14), a processor for deriving from the time interval a

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time delay corresponding to approximately the end of the T-wave (e.g. Fig. 3), A trigger system initiated by an output of the processor or embodied within said processor for applying a train of electrical stimulation pulses at a time related to the end of the time delay (e.g. Fig. 3b), wherein the processor is adapted to generate a first rain of electrical stimulation pulses having a first frequency and a first interval between successive pulses to induce an initial muscle contraction (e.g. column 9, lines 31 – 37), but fails to teach further electrical stimulation pulses that maintain muscle contraction with a reduced energy input. Karasev teaches it is known to use further electrical stimulation pulses that maintain muscle contraction with a reduced energy input (e.g. column 5, line 67 – column 6, line 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation pulses as taught by Krikorian with the further stimulation pulses as taught by Karasev since such a modification would provide the predictable results of effectively treating a target area while using reduced energy.

Regarding **claim 54**, Krikorian discloses the processor is adapted to make a determination for successive pairs of signal peaks of a value corresponding to the time interval between the successive pairs of signal peaks (e.g. column 4, line 66 – column 5, line 7).

Regarding **claim 55**, Krikorian discloses delivering stimulation at intervals that are within a range of 5% before the end of the T wave and up to 45 % after the end of the T wave (e.g. Fig. 3).

Regarding **claim 56 and 61**, Krikorian discloses a plurality of biphasic signal

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pulses (e.g. Fig. 3).

Regarding **claims 57, 58, 60, and 62**, Krikorian in view of Karasev discloses the claimed invention except for a pulse repetition frequency of 150 Hz or 40 Hz and a pulse duration 3 to 10 ms and an interval of 15 to 45 ms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pulses and intervals as taught by Krikorian in view of Karasev, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233] and/or since it has been held that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F. 2d 775, 227 USPQ (Please see MPEP 2144.05).

Regarding **claims 63 – 65**, Krikorian discloses the interval between said further electrical stimulation pulses is selected to be greater than an interval between a signal being initiated at said sensor by a new R-peak and a time delay until this signal has been processed and that the further electrical stimulation pulses are terminated at a time in the range from 85% to 90% of the preceding R-R path length (e.g. Fig. 3).

Regarding **claim 66**, Krikorian discloses inhibiting further electrical stimulation until a time after the projected end of the T-wave in a subsequent heart cycle (e.g. column 7, lines 56 – 59; At the R wave a timer produces a pulse which sets a latch. The latch is not reset until the delay time is over. Thus, any premature R waves are not

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recorded during this time and no stimulation pulses are produced until a time after the projected end of the T-wave).

Regarding **claims 67 and 68**, Krikorian discloses the claimed invention except for varying the pulse repetition frequency. Karasev teaches it is known to vary the pulse repetition frequency (e.g. column 3, lines 4 - 21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation pulses as taught by Krikorian with the varying stimulation as taught by Karasev, since such a modification would provide the predictable results of optimizing the therapy in order to maintain contraction of the target area.

Regarding **claims 69 and 70**, Krikorian varying an amplitude and shape of the pulses (e.g. column 9, lines 24 – 30).

Regarding **claims 71 and 72**, Krikorian discloses an electrocardiograph (e.g. 14) and a non-electric sensor (e.g. 36).

Regarding **claim 73**, Krikorian discloses the non-electric sensor is selected from the group comprising a non-invasive, aortic pressure measurement device, an invasive aortic pressure measurement device, and a noise detection device adapted to detect the closing of the heart valves (e.g. 36).

Regarding **claims 74 and 75**, Krikorian discloses a plurality of output channels for applying electrical stimulation (e.g. 18, 20, and 40).

Regarding **claims 81 and 82**, Krikorian discloses intervals are present between the initial electrical stimulation and the first train and between sequential trains and the

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pulses in any train can have amplitudes of any desired level and different amplitudes within the same train (e.g. Fig. 3).

8. Claims 59 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krikorian in view of Karasev et al. as applied to claim 53 above, and further in view of Wickham (USPN 3,983,881).

Regarding **claims 59 and 80**, Krikorian in view of Karasev discloses the claimed invention except for the pulses of the first train have a pulse width lower than a pulse interval between said pulses. Wickham teaches it is known to use pulses that have a pulse width lower than a pulse interval between the pulses (e.g. Fig. 3a). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pulses as taught by Krikorian in view of Karasev with the pulses as taught by Wickham, since such a modification would provide the predictable results of optimizing the therapy in order to maintain contraction of the target area.

9. Claims 76 – 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krikorian et al. in view of Karasev et al. as applied to claim 75 above, and further in view of Tong et al. (US PG PUB 2004/0082979).

Regarding **claims 76 – 79**, Krikorian in view of Karasev discloses the claimed invention except for each channel group has the same number of channels and the same delay time. Tong teaches it is known to use a plurality of channel groups having the same number of channels and the same time delay (e.g. paragraph 70). It would

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have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation channels as taught by Krikorian in view of Karasev with the channel groups having the same number of channels and the same delay time as taught by Tong, since such a modification would provide the predictable results of synchronizing stimulation among a plurality of target sites.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is (571)270-1895. The examiner can normally be reached on M-F, 8:00 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. D./
Examiner, Art Unit 3762

/Scott M. Getzow/
Primary Examiner, Art Unit 3762